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EXAMINER

SCHNIZER, RICHARD A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 07/30/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/295,464

Applicant(s)

ONG ET AL.

Examiner

Richard Schnizer

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,9,12,13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 and 15 is/are allowed.
- 6) ☒ Claim(s) 1,3-6,12,13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/02 has been entered.

An amendment and an IDS were received and entered as Paper Nos. 17 and 18 on 5/13/02 and 6/17/02, respectively. Claims 2 and 14 were canceled as requested. Claims 1, 3-6, 9, 12, 13, and 15-19 are pending and under consideration in this Office Action.

The previously indicated allowability of claim 12 is withdrawn in view of a new ground of rejection under 35 USC 102, set forth below.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 9, 12, 13, and 15-19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for integration of a

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DNA construct into a target gene having expression restricted to a specific eukaryotic tissue or specialized eukaryotic cell *in vitro* or in a mouse, wherein two DNA constructs encoding separate indicator components are integrated into a cell, which is not a non-mouse ES cell, and which is subsequently used to form a tissue or a specialized cell *in vitro* or to form a mouse, does not reasonably provide enablement for the use of ES cells from an organism other than a mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons of record in Paper No. 10.

Claims 1, 3-6 and 16-18 are directed to methods of screening for insertion of a DNA construct into a target gene having expression restricted to a specific eukaryotic tissue or specialized eukaryotic cell. Claim 13 is directed to cells which are intended to be used in the methods of claims 1-6 and 16-18, and are included in the rejection for that reason.

The methods of claims 1, 3-6 and 16-18 require the production of tissue or specialized cells. This limitation, when read in light of the specification, or in light of claim 19, can be considered to encompass the production of non-mouse transgenic animals which comprise the nucleic acid constructs of the invention. The specification fails to enable this scope of the invention for the reasons given in Paper Nos. 6 and 10. Briefly, the PTO has established the position that, at the time of the invention, non-mouse ES cells could not be used in processes which require transfection and/or selection procedures, while still retaining pluripotency. In other words the specification has not taught how to make non-mouse transgenic animals

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comprising the DNA constructs of the invention, and the specification has not taught how to induce non-mouse ES cells to differentiate into any type of specialized cell or tissue after transfection and/or selection procedures.

***Response to Arguments***

Applicant's arguments filed 5/13/02 have been fully considered but they are not persuasive.

Applicant asserts at page 4 of the response that the rejection is rendered moot by limiting the claims to specify murine ES cells. This is unpersuasive because the term murine embraces non-mouse species such as rats. See attached definition from Merriam Webster's Collegiate Dictionary, 10th Edition.

The rejection may be overcome by substituting the word "mouse" for each instance of the word "murine".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Zambrowicz et al (US Patent 6,207,371, issued 3/27/01).

Zambrowicz teaches a vector comprising the combination of a 3' exon trap and a promoter trap, each of which could separately be used for integration into the genome of a eukaryotic cell. See Fig. 7, VICTR 20. The 3' exon trap comprises a promoter operably linked to a selectable marker. The promoter trap comprises in the 5' to 3' direction, a splice acceptor, a selectable marker, and an IRES element. The selectable markers are equivalent to the indicator components of the instant claims. It is noted that Fig. 7 depicts the IRES element as occurring 5' of the selectable marker, however, at column 13, lines 30-35, Zambrowicz allows for the incorporation of an IRES element 3' to the selectable marker. The instant claims also require a tissue-restricted promoter. Zambrowicz allows for the use of such promoters at column 14, lines 51-60. Finally Zambrowicz teaches that the vector should be used for the transformation of mouse ES cells. See column 15, lines 64-66; column 16, lines 35-40; and column 22, lines 15-18.

Thus Zambrowicz anticipates the claims.

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***Conclusion***

Claims 9 and 15 are allowable. Claims 1, 3-6, and 16-19 are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.



**JAMES KETTER  
PRIMARY EXAMINER**